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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,547	02/12/2002	Rory A.J. Curtis	MPI01-019P1RNM	6620

7590 09/30/2004

Millennium Pharmaceuticals, Inc.
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EXAMINER	
HUNNICUTT, RACHEL KAPUST	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,547	CURTIS, RORY A.J.	
	Examiner	Art Unit	
	Rachel K. Hunnicutt	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,12 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,12 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0704*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

Applicant's amendment filed July 8, 2004 is acknowledged. Claims 8-11 and 13-22 have been canceled. Claims 1, 2, 5, 12, and 23 are amended. Claims 1-7, 12, and 23-25 are pending and under consideration. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

The objection to the disclosure regarding embedded hyperlinks is withdrawn in response to Applicant's amendments to the specification.

The objection to the specification regarding the use of trademarks is withdrawn in response to Applicant's amendments to the specification.

The rejection of claims 5, 6, 23, and 24 under 35 U.S.C. 101 because the claimed invention was directed to non-statutory subject matter is withdrawn in response to Applicant's amendments to the claims.

The rejection of claims 1, 3-7, 12, 23, and 24 under 35 U.S.C. 112, first paragraph, for lack of enablement, is withdrawn in response to Applicant's amendments to the claims.

The rejection of claims 1, 3-7, 12, 23, and 24 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement, is withdrawn in response to Applicant's amendments to the claims.

The rejection of claims 1-7, 12, and 23-25 under 35 U.S.C. 102(a) and (e) as being anticipated by Schlegel *et al.* (WO 01/60860) is withdrawn. The current application has a priority date earlier than the priority date of Schlegel *et al.*

The rejection of claims 1, 3-7, 12, and 23-24 under 35 U.S.C. 102(a) and (e) as being anticipated by Tang *et al.* (U.S. Patent Application Publication 2003/0219745) is withdrawn. The declaration filed on July 8, 2004 under 37 CFR 1.131 is sufficient to overcome the Tang *et al.* reference.

The rejection of claims 1, 3-7, 12, and 23-24 under 35 U.S.C. 102(a) and (e) as being anticipated by Lee *et al.* is withdrawn in response to Applicant's amendments to the claims.

Claim Rejections - 35 USC § 101

The rejection of claims 1-7, 12, and 23-25 under 35 U.S.C. 101 is maintained for reasons of record on p. 4-5 of the office action of paper no. 0304.

Applicant argues on p. 11 of the response that tissue-specific expression of the 25466 nucleic acid is specific to the nucleic acid. Applicant also argues that the 25466 nucleic acid has a substantial utility in that it can act as a diagnostic agent for cellular proliferative and/or differentiative disorders. Applicant refers to Example 12 of the Utility Guidelines as support for the argument.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated in the office action of paper no. 0304, tissue-specific expression such as that found on p. 13 is not specific to the claimed polynucleotide. It does not depend on any characteristics of the nucleic acid molecule itself. Regarding Applicant's argument that the 25466 nucleic acid has a substantial utility as being used as a diagnostic agent for cellular proliferative and/or differentiative disorders, utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. The asserted utility of being a diagnostic agent for cellular proliferative and/or differentiative disorders requires carrying out further research to reasonably confirm a "real world" use. As of the time of the filing, the specification provides no evidence that Applicant has determined whether the 25466 nucleic acid is strongly correlated with either malignant cancers or benign tumors. The specification does not teach whether the "tumor tissue" used by Applicant was malignant or benign. All Applicant has provided is the statement that

levels of 25466 are high in normal ovary cells and low in ovarian tumor cells. This is in contrast to the example in the Utility Guidelines, which taught that a receptor was present in cell membranes of melanoma cells whereas it was not present in the cell membrane of normal skin cells. Such a receptor can be used to diagnose melanoma because the specification disclosed that it was not found in normal skin cells. In the current application, Applicant refers to high, medium, low, and trace levels of expression, but does not provide data which would enable one of skill in the art to diagnose any particular cancer.

It is important to know whether cell lines or biopsies were used, because the expression of markers often differs between expression in cell lines and actual expression in the patient's cancerous tissue. Bover *et al.* (1998, Cell. Mol. Biol. 44(3): 493-504) teach that expression of markers was heterogeneous between an in vitro growing cell line and a xenotransplanted tumor growing in nude mice. An oncogene was amplified in the patient's primary tumor, whereas no amplification was found in the corresponding cell line. Bover *et al.* teach that the differences between the patient's tumor, the cell line, and the nude tumors are probably due to clonal expansion of cell variants not present in the original tumor. The current application is silent as to whether cell lines or biopsies were used, thus one of skill in the art would not know whether the nucleic acid of the claimed invention would be amplified in a real tumor or whether it is merely due to clonal expansion of a cell line.

Applicant does not provide guidance as to how different the levels are, what kind of tumor they tested, whether they were using cell lines or biopsies, or how many samples were tested. Further research would be required to determine how and if the claimed nucleic acid molecule is involved in any disease and whether or not it is a diagnostic marker for any disease.

Claim Rejections - 35 USC § 112

The rejection of claims 1-7, 12, and 23-25 under 35 U.S.C. 112, first paragraph, because since the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility, and one skilled in the art would not know how to use the claimed invention, is maintained for reasons of record on p. 6 of the office action of paper no. 0304.

The rejection of claims 1, 3-7, 12, 23, and 24 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons of record on p. 7-9 of paper no. 0304. Applicants argue that because they have added the functional limitation that the encoded protein must bind a monocarboxylated ion, the claimed allelic variants comply with the written description requirement.

Applicant's arguments have been considered but have not been found to be persuasive. In this case, Applicant provides no information as to the structures of the allelic variants or the fragments of nucleic acid molecules. The only information provided is that they are allelic variants of a 25466 protein and the nucleic acid sequence encoding the allelic variant hybridizes to SEQ ID NO: 1. Applicant is claiming a species which has not been sufficiently described, *i.e.* Applicant is claiming sequences that have not yet been identified. Only once the nucleic acid molecules have been sequenced and their functions have been determined can a person of skill in the art determine that the nucleic acid molecules are allelic variants of a 25466 protein. One of skill in the art would not be able to recognize an allelic variant until the protein is expressed and the activity is assayed. Accordingly, one of skill in the art would doubt that Applicant had possession of the claimed species at the time the application was filed.

Conclusion

NO CLAIMS ARE ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
9/27/04